IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., AND INCEPT LLC,

Plaintiffs,

v.

HYPERBRANCH MEDICAL TECHNOLOGY, INC.,

Defendant.

C.A. No. 15-819-LPS-CJB

REDACTED - PUBLIC VERSION

[PROPOSED] FINAL PRETRIAL ORDER

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May 8, 2018

Redacted Version: May 16, 2018

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This matter comes before the Court at a final pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. Pursuant to Local Rule 16.3(c) and the form Proposed Final Pretrial Order available from Judge Stark's website (http://www.ded.uscourts.gov/judge/chief-judge-leonard-p-stark) (hereinafter "the form Proposed Pretrial Order"), Plaintiffs Integra LifeSciences Corporation, Integra LifeSciences Sales LLC, Confluent Surgical, Inc. (collectively "Integra") and Incept LLC (collectively with Integra, "Plaintiffs") and Defendant HyperBranch Medical Technology, Inc. ("Defendant" or "HyperBranch"), having conferred among themselves hereby submit the following Proposed Final Pretrial Order. This Final Pretrial Order is divided into sections that correspond to the sections of the form Proposed Pretrial Order. The Pretrial Conference in this action will be held on May 15, 2018 at 10:00 a.m., and a jury trial is currently scheduled to begin on May 29, 2018 and conclude by June 8, 2018.

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I. Nature of the Case

- 1. This is a civil action for patent infringement arising under Title 35 of the United States Code.
- 2. Plaintiff Incept LLC owns U.S. Patent No. 7,009,034 ("the '034 patent"), entitled "Biocompatible Crosslinked Polymers"; U.S. Patent No. 7,592,418 ("the '418 patent"), entitled "Biocompatible Crosslinked Polymers with Visualization Agents"; U.S. Patent No. 7,332,566 ("the '566 patent"), entitled "Biocompatible Crosslinked Polymers with Visualization Agents"; and U.S. Patent No. 8,003,705 ("the '3,705 patent"), entitled "Biocompatible Hydrogels Made with Small Molecule Precursors" (collectively "the patents-in-suit").
- 3. Plaintiff Confluent Surgical Inc. and its affiliates are the exclusive licensees of the patents-in-suit in the field of "use as a surgical sealant to seal against leaks of cerebro spinal fluid, air, urine, bile, blood or bowel contents from organs or tissues or to seal against open

surgical bleeding (non-vascular access)" with rights to enforce for past and current infringement.

Plaintiffs Integra LifeSciences Corporation and Integra LifeSciences Sales LLC (collectively "Integra") are affiliates of Confluent under the license.

- 4. On September 15, 2015, Plaintiffs filed a Complaint for infringement of the patents-in-suit.
- 5. On October 28, 2015, Defendant filed its Answer and Counterclaims to the Complaint.
- 6. Pursuant to the Court's authority to manage the issues presented to the jury, the allegations that HyperBranch infringes the patents-in-suit have been narrowed to the following claims (hereinafter "the asserted claims") either literally or under the doctrine of equivalents with respect to the following instrumentalities (hereinafter "the accused products"). With respect to infringement allegations under 271(a), (b), or (c), such allegations are limited to only the Adherus AutoSpray Dural Sealant and the Adherus AutoSpray Extended Tip (ET) Dural Sealant.

	Asserted Claims			
Patent	Adherus Spinal Sealant Adherus Dural Sealant, Adherus AutoSpray			
		Dural Sealant, Adherus AutoSpray Extended		
		Tip (ET) Dural Sealant		
7,009,034	20	10, 20		
7,592,418	8, 23	8, 23		
7,332,566	4	4		
8,003,705	4, 6, 13	4, 6, 13		

7. Plaintiffs assert that HyperBranch infringes the asserted claims literally or under the doctrine of equivalents by making, using, selling, offering for sale, importing or exporting one or more of the above accused products. Particularly, Plaintiffs assert that HyperBranch's infringement of the asserted claims is pursuant to the following sections of 35 United States Code:

Asserted Claim	§ 271(a)	§ 271(b)	§ 271(c)	§ 271(f)(1)	§ 271(f)(2)
'034 Patent, Claim 10	X^1	X	X		
'034 Patent, Claim 20	X	X	X		
'418 Patent, Claim 8	X	X	X		
'418 Patent, Claim 23	X	X	X		
'566 Patent, Claim 4	X^1	X	X	X	X
'3,705 Patent, Claim 4 ²	X	X	X	X	X
'3,705 Patent, Claim 6	X	X	X	X	X
'3,705 Patent Claim 13	X	X	X		

Plaintiffs seek a judgment that HyperBranch has infringed the asserted claims of the patents-insuit, injunctive relief, and damages, including prejudgment interest and increased damages, and seek post-judgment compensation. Plaintiffs also seek their attorneys' fees, costs and expenses incurred prosecuting this action.

8. HyperBranch denies infringement of the asserted claims of the patents-in-suit and alleges that the asserted claims of the patents-in-suit are invalid as anticipated or obvious over prior art and/or as indefinite or lacking sufficient written description or enablement under 35 U.S.C. § 112.³ HyperBranch also denies that Plaintiffs are entitled to injunctive relief. HyperBranch has also asserted the equitable defense of equitable estoppel. HyperBranch proposes that this defense be presented during the jury trial for an advisory verdict. Plaintiffs do not believe an advisory verdict from the jury on this issue is necessary. HyperBranch also seeks its attorneys' fees, costs and expenses incurred defending this action.

II. Jurisdiction

1. This is an action for patent infringement that arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.* that seeks damages and injunctive relief.

¹ See infra, Section XV.B.1, for argument on the parties' dispute related to this issue.

² See infra, Section XV.B.1, for argument on the parties' dispute related to this issue.

³ See infra, Section XV.B.2, for argument on the parties' dispute related to this issue.

- 2. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). No party contests subject matter jurisdiction
- 3. This Court has personal jurisdiction over the parties. For purposes of this litigation only, no party contests personal jurisdiction.
- 4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b). HyperBranch denies that venue is convenient in this Judicial District, but for purposes of this litigation only, no party currently contests venue.

III. Facts

A. Uncontested Facts

Any party, with prior notice to all other parties, may read any or all of the uncontested facts to the jury or Court, and will be charged for the time used to do so. The facts which are not disputed or have been agreed to or stipulated to by the parties are attached as **Exhibit 1**.⁴

B. Contested Facts

Plaintiffs' statements of fact of what they intend to prove in support of their claims and/or defenses is attached as **Exhibit 2**. Defendant's statements of fact of what it intends to prove in support of its claims and/or defenses is attached as **Exhibit 3**.⁵

IV. Issues of Law

Plaintiffs' statement of the issues of law which any party contends remain to be litigated, including citation of authorities relied upon by Plaintiffs, is attached as **Exhibit 4**. Defendant's statement of the issues of law which any party contends remain to be litigated, including citation of authorities relied upon by Defendant, is attached as **Exhibit 5**.

⁴ See infra, Section XV.B.3, for argument on the parties' dispute related to this issue.

⁵ See infra, Section XV.B.3(a) for argument on the parties dispute related to this issue.

V. Witnesses

Any witness not listed herein will be precluded from testifying, absent good cause shown. In the absence of an alternative agreement between the parties, fact witnesses will be sequestered. Also, unless the parties reach an alternative agreement, the order of the presentation of evidence will follow the burden of proof.

Phase I: Plaintiffs' case-in-chief on infringement and damages

Phase II: Defendant's response on infringement and damages and case-in-chief on invalidity and Defendant's affirmative defense of equitable estoppel

Phase III: Plaintiffs' rebuttal on infringement and damages and response on invalidity and Defendant's affirmative defense of equitable estoppel

Phase IV: Defendant's rebuttal on invalidity and its affirmative defense of equitable estoppel

No later than 7:00 p.m. two (2) calendar days before a witness is to be called at trial (*i.e.*, Sunday evening for a witness to be called on Tuesday), the party offering the witness will provide to the other party the names and order of witnesses to be called (both live and by deposition). No later than 7:00 p.m. the day before their introduction (*i.e.*, Monday evening for a witness to be called on Tuesday), the offering party shall provide to the other party any update or change of the names and order of witnesses to be called (both live and by deposition). Any update or change shall not be used to identify and call a witness in the first instance absent agreement of the parties or good cause.

The identification of deposition designations and the resolution of objections to such designations for any witness to be called by deposition shall be dealt with as set forth in Section V.C. below. The identification of exhibits to be used with such witnesses and the resolution of any objections thereto shall be dealt with as set forth in Section V.A. below. The service of

demonstratives to be used with such witnesses and the resolution of any objections thereto shall be dealt with as set forth in Section VI.B. below.

A. List of Witnesses the Plaintiffs Expect to Call

Plaintiffs' witness list is provided below. Subject to the availability of each witness at the time of trial, Plaintiffs intend to call the following witnesses either by live testimony or deposition. Plaintiffs reserve the right to revise, amend, supplement, or modify their List of Expert and Non-Expert Witnesses based on any pretrial rulings by the Court and/or to address any additional issues, arguments, evidence or other developments in the case, including edits to the draft pretrial order, any meet and confers or other negotiations between the parties, pending and anticipated motions, and similar developments. Plaintiffs reserve the right to amend their answering/rebuttal witness list in view of events at trial or other developments, including evidentiary rulings or other rulings by the Court. Inclusion of a witness on this list does not require Plaintiffs to call that witness (either live or by deposition) to testify and does not imply or establish that Plaintiffs have the power to compel the live testimony of that witness or make that witness available to the Defendant. Further, the inclusion of a witness on this list is not an admission that Plaintiffs agree the witness should necessarily be permitted to testify if called by HyperBranch and does not waive Plaintiffs' objections to all or part of the witness's testimony. Should any witness currently identified as testifying live become unavailable before trial, Plaintiffs reserve the right to call the witness by deposition. In addition to the witnesses identified below, Plaintiffs reserve the right to call anyone appearing on HyperBranch's witness list or as a corporate representative of HyperBranch at trial.

1. Expert witnesses

a. <u>Dr. Jimmy Mays</u> – Dr. Mays is a technical expert witness with expertise in the field of polymers (including hydrogels), polymer design, use and manufacture. Dr. Mays will testify consistent with his

- expert reports, including on the issues of infringement and validity, nexus, and will also rebut any opinions of Dr. Lowman, Dr. Flombaum (if Defendant's objections to D.I. 672 are sustained), or Mr. Kidder on matters within his expertise.
- b. **Mr. John Jarosz** Mr. Jarosz is an economics expert with expertise in evaluating monetary and non-monetary damages with respect to intellectual property infringement including lost profits (including lost sales and price erosion), reasonable royalty damages, cost and expense information, and assessing the market for and commercial success of patented products including assessing the causal nexus for the commercial success of the patented products. Plaintiffs also contend that Mr. Jarosz expertise extends into evaluating monetary and nonmonetary damages with respect to irreparable harm, balancing the hardships of a permanent injunction on the parties to the litigation, and assessing the public interest with respect to a permanent injunction. Mr. Jarosz will testify consistent with his expert reports (including any supplemental calculations consistent with the parties' respective supplementation of their respective financial information) in this matter, and will also rebut any opinions of Dr. Lowman, Dr. Flombaum (if Defendant's objections to D.I. 672 are sustained) or Mr. Kidder on matters within his expertise.⁶
- c. <u>Dr. Dennis Rivet</u> Dr. Rivet is a technical expert witness and experienced neuro and spinal surgeon, including the procedures used by neurosurgeons in using new equipment in a surgical environment. Dr. Rivet will testify consistent with his expert reports, including on the issues of infringement and validity, use of the patented and accused dural sealant products and other products used for dural sealing in a surgical environment, the benefits of use of the patented dural sealants over use of other sealants, how a neurosurgeon would the Instructions for Use provided with the patented and accused dural sealants and will rebut any opinions of Dr. Lowman, Dr. Flombaum (if Defendant's objections to D.I. 672 are sustained), or Mr. Kidder on matters within his expertise. Additionally, Dr. Rivet may offer opinion testimony under F.R.E. 701 based on his experience as a physician.
- d. <u>Dr. Mark Distefano</u> Dr. Distefano is a technical expert witness with expertise in the field of chemistry and medicinal chemistry, including protein chemistry, polymers of amino acid linked via amide bonds, and therapeutic and biotechnology applications. Dr. Distefano will testify consistent with his expert reports on issues of infringement, validity and biocompatible degradable hydrogels and will rebut

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⁶ See infra, Section XV.B.4, for argument on the parties' dispute related to this issue.

opinions of Dr. Lowman, Dr. Flombaum (if Defendant's objections to D.I. 672 are sustained) or Mr. Kidder on matters within his expertise.

2. Non-expert witnesses (* indicates the witness is currently anticipated being called live if called at all)

- a. Thomas Harrison*⁷
- b. Curtis Lenox*
- c. Steve Bennett*
- d. Eva Tan*
- e. Amarpreet Sawhney*
- f. Jason Fortier
- g. John M. Tew, Jr.
- h. G. Alexander West, M.D.
- i. Carl Hardwidge, M.D.
- i. Kost Elisevich
- k. Brett Pfeiffle
- l. Terry Maxwell
- m. Sacha Bartlett
- n. Paul Grundy
- o. Emad Shenouda
- p. George Strang
- q. Hoi Sang U
- r. Madelyn Uy
- s. Kerry Potter
- t. John Nail

⁷ See infra, Section XV.B.5, for argument on the parties' dispute related to this issue.

- u. Peter J. Edelman
- v. Christine L'Heureux
- w. Chandrashekhar P. Pathak
- x. Dr. Jay Howington
- y. Dr. Volker R. Jacobs⁸
- z. Dr. L. Mettler⁹
- aa. Any 30(b)(6) Witness Officer, or Employee of HyperBranch that is not appearing live

B. List of Witnesses Defendant Expects to Call

Defendant's witness list is provided below. Subject to the availability of each witness at the time of trial, Defendant intends to call the following witnesses either by live testimony or deposition. Defendant reserves the right to revise, amend, supplement, or modify its List of Expert and Non-Expert Witnesses based on any pretrial rulings by the Court and/or to address any additional issues, arguments, evidence or other developments in the case, including edits to the draft pretrial order, any meet and confers or other negotiations between the parties, pending and anticipated motions, and similar developments. Defendant reserves the right to amend its answering/rebuttal witness list in view of events at trial or other developments, including evidentiary rulings or other rulings by the Court. Inclusion of a witness on this list does not require Defendant to call that witness to testify (either live or by deposition) and does not imply or establish that Defendant has the power to compel the live testimony of that witness or make that witness available to the Plaintiffs. Further, the inclusion of a witness on this list is not an admission that Defendant agrees the witness should necessarily be permitted to testify if called by Plaintiffs and does not waive Defendant's objections to all or part of the witness's testimony.

⁸ See infra, Section XV.B.5, for argument on the parties' dispute related to this issue.

⁹ See infra, Section XV.B.5, for argument on the parties' dispute related to this issue.

Should any witness currently identified as testifying live become unavailable before trial,

Defendant reserves the right to call the witness by deposition. In addition to the witnesses

identified below, Defendant reserves the right to call anyone appearing on Plaintiffs' witness list

or as a corporate representative of Plaintiffs at trial.

1. Expert witnesses

- a. <u>Dr. Anthony Lowman</u>¹⁰ Dr. Lowman is a technical expert witness with expertise in the field of polymeric hydrogel research and development and the use of polymeric hydrogel materials in medical applications, including biocompatibility and histological testing. Dr. Lowman will testify consistent with his expert reports, including on the issues of non-infringement and invalidity, and will also rebut any opinions of Dr. Mays, Dr. Distefano, Dr. Rivet, or Mr. Jarosz on matters within his expertise.
- b. <u>Dr. Jonathan Flombaum</u>¹¹ Dr. Flombaum is an expert in visual perception, cognition, and memory, including how human observers recognize and remember objects and their properties. Dr. Flombaum will testify consistent with his expert reports, including on the issues of non-infringement and invalidity, and will also rebut any opinions of Dr. Mays, Dr. Distefano, Dr. Rivet, or Mr. Jarosz on matters within his expertise.
- c. <u>Dr. Chrys Wesdemiotis</u>¹² Dr. Wesdemiotis is an expert in polymers and polymer characterization, including the characterization of polymers using mass spectrometry. Dr. Wesdemiotis will testify consistent with his expert report, including on the issue of non-infringement, and will also rebut any opinions of Dr. Mays, Dr. Distefano, Dr. Rivet, or Mr. Jarosz on matters within his expertise.
- d. Mr. Douglas Kidder Mr. Kidder is an economics expert with expertise in evaluating damages with respect to intellectual property and antitrust disputes. Mr. Kidder will testify consistent with his expert reports in this matter, and will also rebut any opinions of Dr. Mays, Dr. Distefano, Dr. Rivet, or Mr. Jarosz on matters within his expertise.

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¹⁰ See infra, Section XV.B.4, for argument on the parties' dispute related to this issue.

¹¹ See infra, Section XV.B.4, for argument on the parties' dispute related to this issue.

¹² See infra, Section XV.B.4, for argument on the parties' dispute related to this issue.

2. Non-expert witnesses (*indicates the witness is currently anticipated being called live if called at all)

- a. Jeffrey G. Clark*
- b. Michael Carnahan*
- c. Stuart Rogers*
- d. Curtis Lenox*
- e. Eva Tan*
- f. Steven Bennett*
- g. Amarpreet Sawhney*
- h. Chandrashekhar P. Pathak
- i. Peter G. Edelman
- j. Curtis B. Herbert
- k. Sacha Bartlett
- 1. Africa Carbone
- m. Lawrence Dunn
- n. Kost Elisevich
- o. Jason Fortier
- p. Paul Grundy
- q. Carl Hardwidge
- r. Jay Howington
- s. Christine L'Heureux
- t. Terry Maxwell
- u. John Nail
- v. Brett Pfeiffle

- w. Kerry Potter
- x. Emad Shenouda
- y. George Strang
- z. John Tew Jr.
- aa. Hoi Sang U
- bb. Madelyn Uy
- cc. G. Alexander West
- dd. Any 30(b)(6) Witness, Officer, or Employee of Plaintiffs that is not appearing live

C. Testimony by Deposition

This pretrial order contains the maximum universe of deposition designations, counter-designations, and objections to admission of deposition testimony; none of the foregoing shall be supplemented without approval of all parties or leave of the Court, on good cause shown.

Plaintiffs' deposition designations, Defendant's objections, Defendant's counterdesignations, and Plaintiffs' objections to Defendant's counterdesignations are attached as **Exhibit 6**. Defendant's designations, Plaintiffs' objections, Plaintiffs' counterdesignations, and Defendant's objections to Plaintiff's counterdesignations are attached as **Exhibit 7**. The parties agree that they may designate additional testimony for any witness listed as "anticipated being called live" who does not appear live at trial. The parties further agree that they may use each other's designated testimony. These agreements do not waive any party's objection to the admissibility of any testimony.

The parties agree that each third party witness appearing in a party's case-in-chief by designation of deposition should be called only once during the course of trial.¹³

¹³ See infra, Section XV.B.6, for argument on the parties' dispute related to this issue.

Parties' Joint Proposal for Deposition Designations:

For each witness that a party seeks to call by deposition, that party will provide the other side with a list of final affirmative designations that will be presented by 6:00 p.m. three (3) calendar days before the witness is to be called at trial, the other side will serve objections and counter designations on the proffering party no later than 6:00 p.m. two (2) calendar days before the witness is to be called at trial; the proffering party will serve objections to counterdesignations no later than 8:00 p.m. two (2) calendar days before the witness is to be called at trial, and the parties will meet and confer on these objections no later than 10:00 p.m. the same day.

For any unresolved objections, the party calling the witness by deposition shall use its best effort to submit to the Court, no later than midnight two (2) calendar days before the witness is to be called at trial, on behalf of all parties: (i) a copy of the entire deposition testimony of the witness at issue, clearly highlighting the designations, counter-designations, and pending objections and (ii) a cover letter clearly identifying the pending objections as well as a brief indication (i.e., no more than one sentence per objection) of the basis for the objection and the offering party's response to it. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court (except provision of the letter to the Court by midnight), will result in waiver of the use of the deposition testimony or waiver of objection to the use of the deposition testimony.

All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial.

When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with two copies of the transcript of the designations and

counterdesignations that will be read or played. The designations and counter designations will be played or read in the order taken at the deposition. The parties will be charged for all time that elapses from the time the witness is called until the next witness is called, according to the proportional amount of the designations provided by each party (*i.e.*, the amount of time of their respective designations).

D. Impeachment with Prior Inconsistent Testimony

The parties believe that the Court should allow objections to the use of deposition and other prior testimony for impeachment purposes, including objections based on lack of completeness and/or lack of inconsistency.

E. Objections to Expert Testimony

The parties believe that the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures.

VI. Exhibits

A. Exhibits

This pretrial order contains the maximum universe of exhibits to be used in any party's case-in-chief, as well as all objections to the admission of such exhibits, neither of which shall be supplemented without approval of all parties or leave of the Court, on good cause shown. A list of Plaintiffs' exhibits for its case-in-chief and any objections by Defendant to those exhibits is attached as **Exhibit 8**. A list of Defendant's exhibits for its case-in-chief and any objections by Plaintiffs to those exhibits is attached as **Exhibit 9**.

The parties agree that they may use each other's exhibits listed on the parties' respective exhibit lists. This agreement does not waive any party's objection to the admissibility of that exhibit. No party will remove a document from its exhibit list without agreement from the other

¹⁴ See infra, Section XV.B.7, for argument on the parties' dispute related to this issue.

party, unless it provides the other party the opportunity to add the document to its exhibit list.

The parties further agree that they may add any exhibits introduced at any deposition taken after the submission of this Order to their exhibit list, subject to the other party being given a chance to object to the proposed exhibit as outlined below.

Plaintiffs propose that exhibits not listed may not be admitted at trial unless good cause is shown. Defendant proposes that exhibits not listed may not be used at trial unless good cause is shown. However, exhibits used for purposes of cross-examination are not required to be listed and may be admitted if a proper foundation is laid and any objections to the exhibit have been resolved.

Plaintiffs propose that no exhibit will be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. Defendant objects to this proposal. At some point before the completion of the witness's testimony, any party that has used an exhibit with the witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence, by exhibit number. Exhibits may not be published, displayed, or otherwise shown to the jury until after they have been admitted into evidence. Once admitted, counsel may publish exhibits to the jury without requesting to do so.

A party will provide an identification of exhibits (with the exception of exhibits used solely for cross examination) to be used by 7:00 p.m. the day before their intended use, and objections will be provided no later than 9:00 p.m. the same day. The party proffering a non-documentary exhibit shall make available for inspection any non-documentary trial exhibits, such as physical exhibits, or physical demonstratives that they plan to use at the trial during direct examination of each witness (both live and by deposition) by 7:00 p.m. the day before their intended use. Objections to non-documentary trial exhibits will be provided no later than

9:00 p.m. the same day. The parties will meet and confer on the objections to the exhibits (both documentary and non-documentary) no later than 10:00 p.m. the day before their intended use. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its objections to the Court's attention as the first order of business on the day the witness is called to the witness stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit by the party failing to comply.

Plaintiffs propose that the evidence admitted should be limited to the actual evidence presented by a witness. Defendants propose that before the close of evidence, a party may offer into evidence any exhibits that are not objected to by the other party. Such exhibits shall be identified to the opposing party in accordance with the above procedures.

Plaintiffs propose that exhibits not objected to will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided they are shown to a witness. HyperBranch proposes that exhibits not objected to will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided the above procedures for disclosure are followed.

On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

B. Demonstrative Exhibits

The parties will exchange demonstratives to be used in opening statements by 8:00 p.m. two nights before opening statements. The parties will provide any objections to such demonstratives by 12:00 p.m. (noon) on the day before opening statements. The parties will meet and confer on these objections no later than 3 p.m. on the day before opening statements.

The provision of, objection to and the parties meet and confer with respect to demonstrative exhibits used in connection with direct examination of a witness concur with the same above time frame as non-demonstrative exhibits. If any of the demonstratives change after the deadline, the party intending to use the demonstrative will promptly notify the opposing party of the change(s).

The party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side on physical media (such as a DVD or CD) or as a digital media file. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as a PDF of 8.5 x 11 copies of the exhibits.

This provision does not apply to demonstratives created during testimony or demonstratives to be used for cross-examination, neither of which need to be provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use

If good faith efforts to resolve objections to demonstrative exhibits fail, the objecting party shall bring its objections to the Court's attention as the first order of business on the day of opening statements or the applicable witness is called to the witness stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

VII. Damages

Plaintiffs' itemization of all damages is attached hereto as **Exhibit 10**.

VIII. Bifurcated Trial

The parties do not request a bifurcated trial.

IX. Motions in Limine

Motions *in limine* shall not be separately filed. The parties' motions *in limine* are attached hereto as follows:

Exhibits 11(a)-11(c): Plaintiffs' Motion in Limine No. 1, Defendant's opposition, Plaintiffs'

Reply

Exhibits 12(a)-12(c): Plaintiffs' Motion in Limine No. 2, Defendant's opposition, Plaintiffs'

Reply

Exhibits 13(a)-13(c): Plaintiffs' Motion in Limine No. 3, Defendant's opposition, Plaintiffs'

Reply

Exhibits 14(a)-14(c): Defendant's Motion in Limine No. 1, Plaintiffs' opposition, Defendant's

Reply

Exhibits 15(a)-15(c): Defendant's Motion in Limine No. 2, Plaintiffs' opposition, Defendant's

Reply

Exhibits 16(a)-16(c): Defendant's Motion in Limine No. 3, Plaintiffs' opposition, Defendant's

Reply

All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each SIDE shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument and may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No additional briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

X. Discovery

Pursuant to the Court's February 5, 2018, Oral Order, the parties served supplemental expert reports during the months of January and February 2018. HyperBranch requests that it be permitted to depose Plaintiffs' experts solely on the content of their supplemental reports for which the experts have not yet been deposed in this case. It is plaintiffs' position that the Court only authorized supplemental expert reports, not further depositions of these experts and that no further expert depositions are required. To the extent that the Court permits HyperBranch to again depose Plaintiffs' experts solely on the content of their supplemental reports, the Plaintiffs should be provided the same opportunity with respect to Defendant's expert witnesses.

Pursuant to the Court's oral order during the Status Conference held on April 6, 2018, the parties are working to schedule the video depositions of Dr. Volker R. Jacobs and Dr. L. Mettler (author of the Jacobs reference) which will be conducted prior to trial.

XI. Number of Jurors

There shall be eight jurors. The Court will conduct jury selection through the "struck juror" method, beginning with the Court reading *voir dire* to the jury panel in the courtroom, continuing by meeting with jurors individually in chambers or at sidebar and there addressing any challenges for cause, and concluding with peremptory strikes.

XII. Length of Trial

The trial will be timed. Unless otherwise ordered, time will be charged to a party for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, closing argument, its argument on any motions for judgment as a matter of law, and all sides' argument on objections a party loses (outside the presence of the jury) to another party's deposition testimony, exhibits, demonstrative exhibits, or other argument.

The Courtroom Deputy will keep a running total of trial time used by counsel. If any party uses all of its allotted trial time, the Court will terminate that party's trial presentation.

Considering the Court's procedures for counting time, and considering the nature and extent of the parties' disputes, the parties request forty-two (42) hours—accounting for seven (7) days of trial time with an average of six (6) hours per trial day—for their trial presentation.

XIII. Motions for Judgment as a Matter of Law

Plaintiff's position on the matter of motions for judgment as a matter of law are as follows: (1) motions should be made immediately; (2) motions should be made outside of the jury's presence; and (3) motions may be supplemented in writing. As to the supplementation by writing Plaintiffs current position on the timing and length of the supplementation is as follows if the Court wishes to receive briefing on these issues: (1) supplemental brief in support of motion due within 14 days of the completion of trial; (2) opposition briefs due within 14 days of supplemental brief in support; and (3) reply briefs due within 7 days of opposition brief. The parties should be limited to a single supplemental brief of no more than 20 pages. Opposition briefs will be limited to the same number of pages as the supplemental brief and reply briefs shall be limited to 10 pages.

Defendant's position is that motions for judgment as a matter of law should be made orally, and outside of the jury's presence, at the close of the case-in-chief for the party bearing the burden of proof on the issue, with a written motion not to exceed five (5) pages supporting any oral motions filed within 48 hours, if the Court wishes to receive briefing on the issue. As for the schedule for briefing on renewed motions for judgment as a matter of law, Defendant proposes that the parties and the Court address the schedule for all post-trial briefing after the conclusion of the jury trial.

XIV. Amendments of the Pleadings

The parties do not currently believe that any amendments to the pleadings are necessary.

XV. Additional Matters

A. Confidential Witness Testimony

Plaintiffs anticipate that the courtroom may need to be closed for a portion of the following witnesses' testimony: Thomas Harrison, Eva Tan, Curtis Lenox, John Jarosz, and Douglas Kidder.

Defendant anticipates that the courtroom may need to be closed for a portion of the following witnesses' testimony: Jeffrey G. Clark, Michael Carnahan, Stuart Rogers, Dr. Jimmy Mays, Dr. Mark Distefano, John Jarosz, Dr. Anthony Lowman, Dr. Jonathan Flombaum, Dr. Chrys Wesdemiotis, and Douglas Kidder.

B. Outstanding Disputes

1. Plaintiffs' Infringement Theories

HyperBranch objects to any attempt by Plaintiffs to assert a theory of joint infringement or vicarious liability with respect to alleged direct infringement of claim 10 of the '034 patent or claim 4 of the '566 patent. Any such theory was not disclosed in Plaintiffs' infringement contentions or in their expert reports and should be excluded pursuant to Rule 37 of the Federal Rules of Civil Procedure.

HyperBranch objects to any assertion of doctrine of equivalents for any of the asserted claims of the '3,705 patent. Plaintiffs' infringement contentions never disclosed a doctrine of equivalents theory with respect to the asserted claims of the '3,705 patent. Following submission of expert reports, HyperBranch requested a meet and confer regarding a motion to strike any assertion by Plaintiffs under the doctrine of equivalents for the asserted claims of the '3,705 patent based on their failure to disclose any such infringement theory by equivalents in their

infringement contentions. During that meet and confer, Plaintiffs agreed they would no longer assert doctrine of equivalents for the '3,705 patent and would rely only on a theory of literal, direct infringement for that patent.

2. HyperBranch's Invalidity Theories

Plaintiffs object to Defendant's failure to identify what specific invalidity defenses on which it intends to proceed at trial. It is long past time for Defendant to specifically identify (and be held to that identification) which of its 102, 103, and 112 defenses that it will present at trial. It is highly prejudicial to Plaintiff to allow Defendant to continue to hide the actual invalidity defenses that it will present at trial and effectively present a trial by ambush as Plaintiffs' allocation of trial resources (including time allocated for its rebuttal case) is highly dependent on the number of and specific identification of the actual invalidity defenses that Defendant is presenting at trial. For example, there is no specific identification of the particular 112 defenses (i.e., an identification of the specific claim language of the specific claim that Defendant asserts fails to comply with a specific requirement of 35 U.S.C. § 112) in the current exhibits to this proposed pretrial order or in the proposed jury instructions. Further, to the extent that Defendant has specifically identified particular grounds under 35 U.S.C. §§102 or 103 with respect to claim 10 of the '034 patent, Defendant should be estopped from presenting those grounds as a defense to claim 10 of the '034 patent as provided in 35 U.S.C. § 315(e)(2), i.e., the grounds that HyperBranch raised or reasonably could have raised during the *inter partes* review. This includes the invalidity grounds listed in Exhibit 3, ¶¶ 127-128.

HyperBranch asserts that it has properly identified the invalidity theories it may present at trial through discovery, expert reports, invalidity contentions, and also by its specific listing of invalidity defenses and theories in the exhibits to this order and its proposed jury instructions. Plaintiffs do not contest that HyperBranch has fully complied with the Court's procedures for

reducing its invalidity grounds (*see* October 2, 2017 Oral Order re D.I. 340) and adequately disclosed those grounds throughout both fact and expert discovery. Instead Plaintiffs are seeking HyperBranch's trial strategy and only wish to limit HyperBranch's ability to respond to and defend itself against Plaintiffs' trial presentation. Plaintiffs have provided no authority for forcing a defendant to disclose their trial strategy and presentation of affirmative defenses before trial begins.

Finally, Plaintiffs' eleventh-hour attempt to limit HyperBranch's assertion of its *successful* IPR invalidity grounds runs contrary to the purpose of the AIA, results in the absurd result of HyperBranch being in a worse position for being successful at the PTAB, contradicts the plain meaning of the term "estoppel," and strips HyperBranch of its due process right to defend itself by denying it the opportunity to be heard on its invalidity defenses. Plaintiffs' strained interpretation of the AIA's estoppel provisions serves only one purpose: to prejudice HyperBranch for successfully invalidating claim 10 of the '034 patent at the PTAB.¹⁵

3. Uncontested Facts

HyperBranch proposes that the following facts are uncontested and should be included in Exhibit 1:

• Claim 10 of the '034 patent is entitled to an invention date of no earlier than November 9, 2001.



¹⁵ HyperBranch notes that Plaintiffs have failed to file a request for rehearing of the PTAB's final written decision finding claim 10 unpatentable. (*See* 04/06/2018 Hearing Tr. at 13:6-8 (Plaintiffs' counsel representing deadline for rehearing as May 3.)

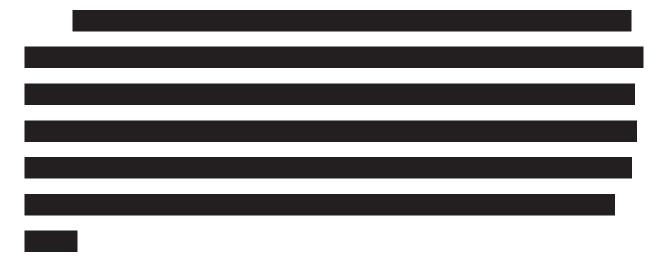
- Some former customers of DuraSeal use fibrin glue instead of DuraSeal.
- Some former customers of DuraSeal no longer purchase DuraSeal for reasons not related to HyperBranch's alleged infringement.
- Not all former customers of DuraSeal have purchased Adherus.

HyperBranch asserts that each of these facts has been conclusively established during discovery, either through requests for admission, interrogatory responses, document production, and/or deposition testimony. During the parties' meet and confer, Plaintiffs admitted that they do not dispute that the Court's orders combined with their discovery responses establish the earliest inventions date for claim 10 of the '034 patent, but believe they must contest the fact for appeal purposes.

Finally, in response to HyperBranch's requests for admission and pursuant to Judge Burke's order overruling their objections and compelling responses (D.I. 343), Plaintiffs have admitted certain facts about their former customers' purchasing habits.

Plaintiffs respond that they do not dispute that the Court's orders prohibit the Plaintiffs from supplementing their discovery response to incorporate a revised date of invention due to a newly introduced prior art argument raised by Defendant (and their expert in his expert report) after the close of discovery (i.e., that the inventors' own prior work, i.e. Dunn et al. describing SprayGel and dated February 2001, inherently had teaches a claim limitation of claim 10, namely "wherein the hydrogel forms within 5 seconds after contact with the substrate") to account for the contingency that if this newly raised inherency argument was found in favor of Defendant, then the inventor's own previous work, i.e. Dunn et al., would also then constitute an earlier date

of invention. As Plaintiffs believe this ruling to be properly preserved for appeal, they cannot agree that any resulting fact from these orders is undisputed, i.e. because Dunn et al. describes a complete conception of the invention of claim 10 and Plaintiffs timely supplemented the conception date under F.R.C.P. 26(e), pending resolution of any appeal



Finally, Plaintiffs believe that the "facts" set forth by HyperBranch do not properly address the entirety of their supplemental response to the requests for admission ordered by the Court.

4. Expert Witnesses

HyperBranch objects to Mr. Jarosz testifying on matters that have been stricken from his expert report or excluded by the Court, including lost profits from lost sales, pursuant to the Court's Order at D.I. 554 and Magistrate Judge Burke's Report and Recommendation at D.I. 658. HyperBranch further objects to Mr. Jarosz testifying on issues related to his opinions on injunctive relief, as such matters will not be presented to the jury.

Plaintiffs object to Dr. Lowman testifying with respect to subjects including but not limited to noninfringement or invalidity positions in his expert report that are based on a claim construction that has been excluded by the Court's Memorandum Order (D.I. 672). HyperBranch has objected to the Court's Memorandum order (D.I. 698). Plaintiffs assert that the effect of the

Court's *Daubert* Ruling with respect to Dr. Lowman extends beyond simply his noninfringement opinions but also affects his opinions on invalidity and the Court should preclude Dr. Lowman from presenting any of the opinion testimony set forth in Plaintiffs' Daubert motion and any other opinion that is tied to Dr. Lowman's excluded requirement of a "color or transparency matching." In addition to his noninfringement opinions that are based on a claim construction that the Court found inconsistent with its claim construction, Dr. Lowman's opinions on at least (1) the alleged invalidity of the predetermined thickness claims due to failure to comply with any one or more of the requirements of 35 U.S.C. Section 112; (2) Dr. Lowman's incorporation of his opinions from the preliminary injunction phase that also rely on this improper claim construction; (3) any critique of Dr. Mays opinions that are based on Dr. Mays having not presented evidence that would satisfy the Dr. Lowman's excluded claim construction requirements; or (4) reliance by Dr. Lowman on evidence (i.e., third party deposition testimony) that allegedly does not meet Dr. Lowman's now excluded construction of the claims.

Plaintiffs object to HyperBranch's identification of Dr. Flombaum as a witness. Pursuant to the Court's Memorandum Order of April 4, 2018 (D.I. 672) all of Dr. Flombaum's substantive testimony was excluded when Plaintiffs' *Daubert* motion was granted. HyperBranch has objected to the Court's Memorandum order (D.I. 698).

Plaintiffs object to Dr. Wesdemiotis testifying as his expert report was limited to issues dealing with U.S. Patent No. 6,566,406, which pursuant to the Court's orders to reduce the number of asserted claims for trial, will not be at issue in the trial. Particularly, Dr. Wesdemiotis opinions are with respect to "the molecular weight of the polyethyleneamine (PEI) polymer in HyperBranch's Adherus AutoSpray Dural Sealant and to evaluate and analyze Dr. Mays' experimental analysis regarding this polymer." The sum of Dr. Wesdemiotis particular opinions

are that the "weight-average molecular weight (Mw) of the branched PEI polymer in

HyperBranch's Accused Products is approximately and that "Dr. Mays' experimental results are incorrect and do not properly measure the molecular weight of the used in the Accused Products. The molecular weight of the was only relevant to the issues dealing with the '406 Patent. There is no opinion in Dr. Wesdemiotis report regarding the chemical composition of the Accused product and the only discussion in Dr. Wesdemiotis report regarding a feature or fundamental nature of the PEI polymer is its molecular weight. Because the weight average molecular weight of the branched PEI polymer is irrelevant to any of the asserted claims going to trial, Dr. Wesdemiotis' testimony is irrelevant to any issue remaining before the Court.

HyperBranch asserts that Dr. Wesdemiotis's testimony remains relevant to issues regarding the chemical composition and features of the Accused Product and is a direct response to experiments performed by Plaintiffs' expert Dr. Mays on which Plaintiffs intend to rely at trial. HyperBranch disagrees that Dr. Wesdemiotis's testimony was limited to issues related to the '406 patent (which is no longer at issue given the Court's ruling at the claim construction stage that the asserted claims are invalid for indefiniteness). Dr. Wesdemiotis' expert report never provided any specific opinions related to infringement or invalidity of the '406 patent, nor was his expert report couched as being solely directed to any individual patents or any legal issues in dispute between the parties. Rather, his expert report is directed to a scientific, factual analysis of the disputed PEI polymer "precursor" in the Accused Products and was submitted in order to rebut the flawed analysis that Plaintiffs and Dr. Mays has relied on throughout this case. Dr. Wesdemiotis is an undisputed expert in the field of polymer analysis, in particular the use of mass spectrometry to analyze polymers. His testimony will demonstrate the fundamental nature

of the analysis of a polymer as well as flaws in the mass spectrometry experiments and results performed by Dr. Mays, which is going to be a key issue at trial. Indeed, Dr. Wesdemiotis has an entire section of his expert report entitled "Dr. Mays' Experimental Analysis is Flawed and Incorrect." Dr. Wesdemiotis will provide the jury with a full explanation of the nature of the disputed PEI polymer in the Accused products so that they will be able to understand why the experiments Dr. Mays intends to present at trial are scientifically invalid. He will also provide the results of his own experiments in order to rebut Dr. Mays' experimental data and the factual conclusions he draws. The technical information directed to the scientific principles and methodologies of experimental polymer analysis is a hotly contested issue in this case and Dr. Wesdemiotis' testimony remains highly relevant to the issues in dispute. During a meet-andconfer, Plaintiffs refused to agree that they would not rely on the experiments performed by Dr. Mays for which Dr. Wesdemiotis served his rebuttal expert report. Dr. Wesdemiotis' experiments and expert testimony are indisputably relevant to the issues at trial concerning the chemical features of the PEI polymer in the Accused Products as well as impeachment of the credibility of Dr. Mays regarding his experimental approaches to support Plaintiffs' allegations of infringement by HyperBranch.

5. Fact Witnesses

HyperBranch objects to Plaintiffs' identification of Mr. Harrison, as he is not listed on Plaintiffs' Rule 26(a) witness list and was not previously identified by Plaintiffs as a potential witness. Pursuant to the Court's Oral Order denying HyperBranch's Motion to Strike Plaintiffs' belated identification of Mr. Thomas Harrison as moot (D.I. 585), HyperBranch renews its Motion (D.I. 582) and incorporates by reference its letter to the Court explaining why Plaintiffs' late identification should be stricken pursuant to Rule 37 and the Third Circuit's *Pennypack* factors (D.I. 583).

Plaintiffs assert that Mr. Harrison was identified during discovery as a potential witness. Particularly, Mr. Harrison (including the identification of his current position as Mr. Lenox's supervisor) was discussed and selected as one of the ten custodians the parties agreed to search and produce documents and things pursuant to the agreed ESI search protocol (Mr. Harrison's name therefore appears on a substantial number of documents produced to the Defendants during discovery). Additionally, Mr. Harrison was identified a number of times in Mr. Lenox's declarations submitted in this case and was identified by name multiple times by multiple rule 30(b)(6) designees of the Integra entities (i.e., Ms. Tan and Mr. Lenox) as an individual they met with to gather facts and information in response to a number of noticed topics. Further, Mr. Lenox also discussed Mr. Harrison's contributions to a number of exhibits introduced by HyperBranch during Mr. Lenox's deposition. Even further, Mr. Harrison (along with Mr. Lenox was specifically identified in the declarations, reports and depositions of Mr. Jarosz as the source of specific factual information that is relevant to Mr. Jarosz' opinions. Plaintiffs have also offered to let HyperBranch depose Mr. Harrison (previously on March 9, 2018) prior to trial. To the extent the Court wants to consider Plaintiffs' position in writing, Plaintiffs' can submit written opposition to Defendant's Motion to Strike (D.I. 582).

HyperBranch objects to Plaintiffs' identification of Drs. Jacobs and Mettler, as they are not listed on Plaintiffs' Rule 26(a) witness list, were not previously identified by Plaintiffs as a potential witness, and HyperBranch did not have the opportunity to depose either of them during fact discovery. The Court allowed Dr. Jacobs' and Dr. Mettler's depositions, but did not resolve the issue of either appearing as a witness at trial. For substantially the same reasons identified for Mr. Harrison's exclusion, HyperBranch believes that Plaintiffs should be precluded from calling Drs. Jacobs and Mettler to testify at trial. HyperBranch further objects to the admission of any

testimony from either Dr. Jacobs or Dr. Mettler at trial because Plaintiffs have failed to make a good faith production of relevant documents from these individuals. To date, Plaintiffs have produced only a single one-page document from Dr. Jacobs in response to the Court's instruction. Plaintiffs have not identified how the search for documents was performed, what relevant repositories were searched, or what types of keywords were utilized in such searches. Additionally, Plaintiffs have not indicated whether Dr. Jacobs and Dr. Mettler have access to institutional records that would also be relevant to a proper cross-examination of these witnesses. HyperBranch believes that, under such circumstances, it will not be able to adequately cross-examine Dr. Jacobs and Dr. Mettler in a manner that is consistent with due process in that it will not have any of the relevant documentary evidence that would demonstrate that both doctors are interested and biased towards supporting Plaintiffs' position in this case, or that would enable HyperBranch to impeach their oral testimony concerning relevant facts from almost 17 years ago.

Plaintiffs assert that Dr. Jacobs and Dr. Mettler are properly identified and that the issue of Dr. Jacobs and Dr. Mettler being a potential witness was resolved by the Court during the teleconference of April 6, 2018. Defendant's baseless allegations only evidence the extent that Defendant will go to mislead by presenting work done on behalf of and at the direction of the inventor's as prior art. All of Defendant's arguments as to what Plaintiffs have not done pursuant to their representation of a good faith production of documents from Dr. Jacobs and Dr. Mettler imposes obligations on Plaintiffs' counsel that were not part of the Court's order but are simply a product of Defendant's imagination. HyperBranch's questions about the scope of the search performed by Dr. Jacobs and Dr. Mettler are more appropriately reserved for their respective depositions.

The parties have agreed to work cooperatively to schedule adverse examination of witnesses who will appear live at trial.

6. Deposition Designations

Plaintiffs assert that with respect to deposition designations of party witnesses who were 30(b)(6) designees or corporate officers, these procedures should also be followed except that counter designations should be prohibited except for those necessary for completeness as the designations constitute admissions of a party opponent and any other "counter-designations" can be presented in the party's rebuttal case through direct examination of the witness (if called live) or presentation of counterdesignations (if not called live). Further, any designations of a 30(b)(6) witness or corporate officer first called live should be excluded as any such designations can adequately be presented during cross-examination of a live witness. HyperBranch's further proposal to require that "witnesses who will appear live at trial for one party's case in chief be made available to be called live as an adverse witness for the opposing party" is improper on its face. See Fed. R. Civ. Pro. 32(a)(3). HyperBranch fails to cite any authority which would require Plaintiffs' to call, for example, Defendant's CEO (and 30(b)(6) designee) Mr. Clark, live in its case-in-chief, as opposed to being able to present certain portions of his previously taken deposition

HyperBranch proposes that 30(b)(6) witnesses be treated the exact same as all other witnesses at trial: with each party being afforded the opportunity to provide counter-designations at the same time as originally played testimony and all deposition testimony played by video be played at the same time. HyperBranch further proposes that witnesses who will appear live at trial for one party's case-in-chief be made available to be called live as an adverse witness for the opposing party. HyperBranch objects to Plaintiffs' improper attempt to limit HyperBranch's opportunity to present counter deposition testimony of its 30(b)(6) witnesses. Showing multiple

deposition clips for the same witness or having to call a live witness to rebut previously played deposition testimony will undoubtedly lead to jury confusion. Plaintiffs provide no authority whatsoever for their novel and confusing proposal.

7. Exhibits

In addition to the objections listed in Exhibit 8, HyperBranch reserves the right to object to any exhibit, including as lacking foundation, as impermissible hearsay under FRE 801 and 802, or lacking personal knowledge, dependent on the manner in which Plaintiffs seek to introduce the exhibit, including to which witness the exhibit is shown.

Plaintiffs assert that HyperBranch's reservation of an objection to "any exhibit for lack of foundation, impermissible hearsay under FRE 801 and 802, or lacking personal knowledge, dependent on the manner in which Plaintiffs seek to introduce the exhibit, including to which witness the exhibit is shown" is improper and any such objections should have been made in Exhibit 8 or be waived. To the extent that the Court allows such additional objections, Plaintiffs reserve the right to object to any exhibit for the same additional reasons that the Court allows HyperBranch to provide additional objections.

8. Equitable Estoppel

Pursuant to Federal Rule 39(c), HyperBranch believes that its equitable estoppel defense should be tried to the jury for an advisory verdict, rather than tried separately to the Court at some time after the jury trial. Trial to a jury for an advisory verdict is appropriate where, as here, factual determinations underlying a finding of equitable estoppel are intertwined with other legal issues. *See Bombardier Recreational Products, Inc. v. Arctic Cat Inc.*, Civ. No. 12-2706 (JRT/LIB), 2017WL 5256741, *2 (D. Minn. Nov. 11, 2017) (denying motion to bifurcate equitable defenses and trying equitable estoppel to advisory jury); *Cedarapids, Inc. v. CMI Corp.*, No. C98-0110 MJM, 1999 WL 33656876, at *3 (N.D. Iowa Oct. 26, 1999) ("In this case,

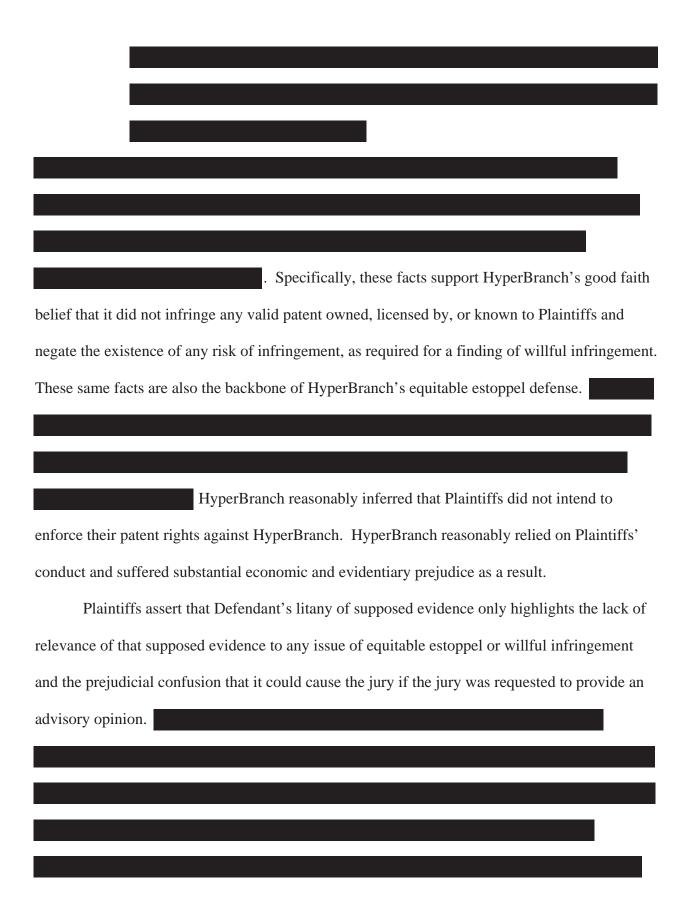
the issues of laches, estoppel and willfulness are intertwined with common factual determinations. . . . Therefore, the court finds that separate trials would be a waste of judicial time and resources."). For example, when a defendant "has chosen to assert the equitable defenses of laches and estoppel, willfulness bears not only on the amount of damages if infringement is proven, but also on whether [the Plaintiff] should be equitably estopped." *Id.* In such a circumstance, "a jury's fact findings common to a legal claim and an equitable defense are to be accepted by the court in ruling on the equitable matter." *Quaker City Gear Works, Inc.* v. *Skil Corp.*, 747 F.2d 1446, 1456, n. 11 (Fed. Cir. 1984).

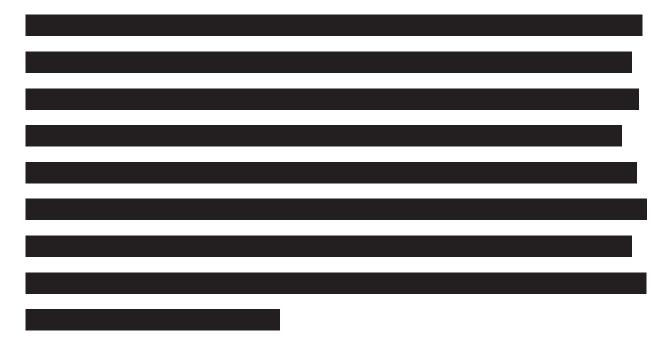
Here, the issues of equitable estoppel and non-willful infringement are inextricably linked. To defend against Plaintiffs' assertion that HyperBranch willfully infringed the asserted patents,

This same evidence also bears on equitable estoppel. For example, HyperBranch will present evidence of the following:

Approximately one month after HyperBranch's OcuSeal product receives approval for use in the European Union,







The issue of whether to submit the defense of equitable estoppel to the jury for an advisory basis is purely discretionary matter for the Court. *See* Fed. R. Civ. Pro. 39(c)("the court, on motion or on its own: (1) may try any issued with an advisory jury); *Carnegie Mellon University v. Marvell Technology Group Ltd.*, Case No. 09-290, 2012 WL 12894751, *3 (W.D. Pa. Nov. 28, 2012)(noting that submission of equitable defense of laches for an advisory verdict is a matter of the Courts Discretion). Defendant, as of the preparation of this PTO, has never submitted a motion requesting an advisory verdict. *Id.*, fn. 2. As noted by the court in *Carnegie Mellon* with respect to the equitable defense of laches,

The Court comments initially that [Defendant] has argued only generally that there are overlapping factual issues between the evidence of laches and the evidence it plans to present with respect to its defense against [Plaintiff]'s claim of willfulness...[Defendant] has only argued in a vague manner that it can meet its burden to present evidence on laches to the jury and this Court, while pointing out that some courts have found it appropriate to submit the issue to the jury on an advisory basis. (Id.). [Defendant]'s inability or unwillingness to raise any specific evidence in support of its defense—through a proffer or otherwise—indicates to the Court that the purpose of the present request for an advisory verdict may be only to mislead or confuse the jury, rather than to legitimately present the defense at trial.

Id., at *2. Similar to the current matter where Defendant has provided no specificity and has not even previously moved for the issue to be given to the jury for an advisory verdict, the court in *Carnegie Mellon* found it appropriate for the court to rule on the equitable issue without an advisory verdict (following scheduled submission of post trial findings of fact and conclusions of law by the parties). *Id.*, *citing*, *McKesson Information Solutions LLC v. The Trizetto Group*, Inc., 2006 WL 940543, at *1, n.1 (D. Del. Apr. 11, 2006) (noting that the equitable defense would be decided in post-trial bench proceeding); *Green*, *Tweed of Delaware*, *Inc. v. DuPont Dow Elastomers*, *L.L.C.*, 281 F. Supp. 2d 767, 768 (E. D. Pa. Aug. 19, 2003)¹⁶. Given the striking similarity in the pertinent surrounding facts in this matter as in the *Carnegie Mellon* matter, plaintiffs assert that resolution of this equitable issue should be accomplished by the Court through post trial brief, thereby minimizing any potential jury confusion.

9. Judicial Estoppel

HyperBranch asserts that Plaintiffs are judicially estopped from challenging the status of VR Jacobs, et al., "SprayGelTM as New Intraperitoneal Adhesion Prevention Method for Use in Laparoscopy and Laparotomy," ISGE 10 Convention, Chicago (March 2001) (the "Jacobs reference") as prior art. During claim construction, Plaintiffs asserted that various preclinical references related to the SprayGel product cited on the face of the patents-in-suit—including the Ferland reference, which was presented at the same conference as Jacobs—constituted prior art to support their claim construction regarding biocompatibility. (*See* D.I. 544 at 4; *see also* D.I. 520 at 4.) The Court adopted Plaintiffs' argument that the Ferland reference constitutes intrinsic evidence, *i.e.*, is prior art, for purposes of claim construction. (*See* D.I. 652 at 8, n.4.) In

¹⁶ Plaintiffs further note that Defendant's citation to the *Quaker City* matter in submitting its position on this issue is inaccurate both in form and in context. Particularly, the quoted language comes from fn. 11 of the *Quaker City* matter and is directed to an issue involving the awarding of costs.

particular, the Court noted that "the Federal Circuit has explained that 'prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence." (See id. (emphasis added.) Thus, a reference must be "prior art" to be considered part of the intrinsic record for purposes of claim construction. Plaintiffs are now judicially estopped from now arguing the contrary, i.e. that Jacobs—which is another preclinical reference related to SprayGel cited on the face of the 034 patent and was presented at the same ISGE 10 conference as Ferland—is not prior art, for the sole purpose of avoiding invalidity. Allowing Plaintiffs to knowingly adopt clearly inconsistent positions regarding the prior art status of the Ferland and Jacobs references from the same conference would grant them an unfair advantage at HyperBranch's expense. See In re Armstrong World Indus., Inc., 432 F.3d 507, 517-18 (3d Cir. 2005) (judicial estoppel factors include "whether the party's position is clearly inconsistent with its earlier position and whether the party changing position would gain an unfair advantage over the opposing party") (citing New Hampshire v. Maine, 532 U.S. 742, 750-51 (2001)).

The inconsistency in Plaintiffs' positions regarding the Ferland and Jacobs references from the ISGE 10 meeting in 2001 is further highlighted by the fact that the Ferland reference explicitly identifies one of the named inventors of the '034 patent as a co-author. Yet, despite this fact—apparent on the face of the Ferland reference—Plaintiffs nevertheless successfully asserted that Ferland is prior art for claim construction. Thus, Plaintiffs knowingly sought to gain an advantage in the litigation by arguing that a reference that actually includes one of the named inventors as a co-author constitutes prior art. In contrast, the Jacobs reference does not include any named inventor as a co-author. Having successfully argued to the Court the prior art status of Ferland, Plaintiffs should not be permitted to adopt the contradictory positions that the

Jacobs reference is not prior art simply because Plaintiffs are now faced with the ramifications of their assertions regarding the prior art status of the Ferland reference.

Plaintiffs contend that HyperBranch's assertion of judicial estoppel follows from a false premise that is clearly belied by the documents cited by HyperBranch. Particularly during claim construction, Plaintiffs argued that Ferland et al (along with other documents cited on the face of the patent were **intrinsic evidence**. See, D.I. 544, p. 4 ("Ferland et al. (intrinsic evidence) evaluating SprayGel describes 'all treated surfaces look normal and appear to be healing normally.""). The Plaintiffs also distinguished the prior art intrinsic evidence from the other intrinsic evidence. See, D.I. 520, p. 4 ("The '034 patent also identifies several prior art patents, including the Wallace patent, as well as the inventors' own preclinical studies on a hydrogel composition known as SprayGel – all of which are **intrinsic evidence**")(emphasis added); The Court acknowledged this distinction by noting that "[t]he Ferland et al. reference regarding SprayGel that Plaintiffs point to as intrinsic evidence" (See, D.I. 652, p. 4. n. 4) as compared to its understanding of plaintiffs assertion that Wallace is intrinsic evidence and prior art. (See, D.I. 652, p. 8, n. 6, "Plaintiffs assert that Wallace is intrinsic evidence...the Federal Circuit has explained that 'prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence.""). Given that there is no clear inconsistency in Plaintiffs position (e.g. Plaintiffs identified Ferland et al as intrinsic evidence but did not admit that it was prior art), the doctrine of judicial estoppel is not applicable. See In re Armstrong World Industries, Inc., 432 F.3d 507, 517-518 (3rd Cir. 2005) (judicial estoppel requires that a party take a position clearly inconsistent with an earlier position).

XVI. Settlement

The parties hereby certify that they have engaged in a good faith effort to explore resolution of this controversy by settlement. These efforts include multiple telephone

conversations and email correspondence exchanged between business principals of the Integra Plaintiffs and Defendants, the last of which occurred in November 2017. The parties have a mediation conference before Judge Burke scheduled for May 16.

IT IS HEREBY ORDERED that this Final Pretrial Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

DATED:	
	CHIEF, UNITED STATES DISTRICT JUDGE

APPROVED AS TO FORM AND SUBSTANCE:

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